K101585

**SECTION 5 - 510(K) SUMMARY** MAY 10 2011

**Date Prepared:** May 4, 2011

**Applicant:**
Johnson & Johnson Healthcare Products,
Division of McNEIL – PPC, Inc.
185 Tabor Road
Morris Plains, NJ 07950

**Contact Person:**
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**Proposed Device:** K-Y® Brand Vaginal Moisturizer

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|---|---|
| Classification Name: | Lubricant, Vaginal, Patient, Latex Compatible |
| Classification: | Class II |
| Product Code: | NUC |
| Regulation: | 21 CFR §884.5300 |
| Document Control No: | K101585 |

**Predicate Device:** K-Y® Brand Jelly Personal Lubricant

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| Regulation Description: | Lubricant, Vaginal, Patient |
| Classification Name: | Lubricant, Patient |
| Classification: | Class I |
| Product Code: | KMJ |
| Regulation: | 21 CFR §880.6375 |
| Document Control No.: | K810310 |

**Description:** K-Y® Brand Vaginal Moisturizer is a non-sterile personal moisturizer formulated to supplement the body's own natural lubricating fluids to provide personal moisturization when vaginal dryness causes discomfort.

**Indication for Use:** K-Y® Brand Vaginal Moisturizer is a personal lubricant, for vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is not compatible with natural rubber latex or synthetic condoms.

**Comparison to the Predicate Device:**

K-Y® Brand Vaginal Moisturizer and the predicate device are similar in all characteristics except:

- Technical Composition – As water based gels, the formulations of the proposed device and the predicate device are substantially equivalent. They each contain ingredients from the same or similar functional categories. Both products have excellent moisturization/lubrication characteristics and similar lubricity. The composition of the proposed device includes additional emollients, lubricants and polymers to enhance the feel and lubricity of the formula. This difference does not negatively affect the safety, effectiveness, or intended use of the device.

- Packaging – The proposed device is packaged in pre-filled applicators to facilitate insertion directly into the vagina while the predicate device is packaged in a tube. The formulation has been determined to be stable in this packaging. This difference does not affect the safety, effectiveness, or intended use of the device.

- Intended Use – The proposed device is not intended for use with condoms as it contains mineral oil which is known to be deleterious to latex condoms. To address this difference, the proposed device will contain the following warning statement:

  DO NOT USE WITH CONDOMS. This lubricant contains mineral oil which may damage the condom.

- Directions for Use – The directions for use of the proposed device differ only in the method of application. The proposed device is inserted directly into the vagina via a pre-filled applicator, while the predicate device is applied directly to the vaginal area or directly to the device being inserted into the vagina. This difference does not affect the safety, effectiveness, or intended use of the device.

Based on the comparisons above, performance data, biocompatibility review and testing, and human use and safety data, we conclude that K-Y® Brand Vaginal Moisturizer and K-Y® Brand Jelly are substantially equivalent.

**Technological Characteristics:**

Formulation: K-Y® Brand Vaginal Moisturizer, is a stable, non-sterile, translucent, aqueous based, preserved, formulated product composed of a combination of emollients, gelling agents, preservatives, vehicles, and an antioxidant. It is non-fragranced, pH balanced, and contains Vitamin E.

Stability: Real time stability date confirms a 2 year shelf life.

**Performance Data:**

Lubricity: Lubricity of K-Y® Brand Vaginal Moisturizer is comparable to the predicate device.

Condom Compatibility: This product has not been shown to be compatible with condoms. Labeling will contain a statement to this effect and a warning not to use with condoms.

Biocompatibility: The following biocompatibility testing has been performed on the current K-Y® Brand Vaginal Moisturizer.

- Agar Overlay Cytotoxicity

The following biocompatibility testing has been performed on a prototype formula of K-Y® Brand Vaginal Moisturizer.

- Rabbit Vaginal Irritation

Human Safety and Use: The following Human Use and Safety testing has been performed on K-Y® Brand Vaginal Moisturizer.

- Exaggerated Human Use (Human Repeat Insult Patch Test)
- In-Home Consumer Use Study

Conclusion: K-Y® Brand Vaginal Moisturizer is safe and well tolerated when used as intended to provide long lasting relief from vaginal dryness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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MAY 10 2011

Re: K101585
Trade/Device Name: K-Y® Brand Vaginal Moisturizer
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: April 29, 2011
Received: May 2, 2011

Dear Dr. LaMotte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## 4. INDICATIONS FOR USE STATEMENT

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|---|---|
| 510(k) Number: | K101585 |
| Device Name: | K-Y® Brand Vaginal Moisturizer |
| Indications for Use: | K-Y® Brand Vaginal Moisturizer is a personal lubricant, for vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.<br><br>This product is not compatible with natural rubber latex or synthetic condoms. |

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use X

*(Per 21 CFR §801.109)*

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K101585